510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

(A)(1) Submitter's name:	Wang & Li, Inc.
Submitter's address:	2026 Coyle Street Brooklyn, NY 11229
Submitter's telephone no.:	(718) 332-8817
Contact Person:	Ann D. McGonigle Regulatory Consultant (508) 358-9114
Date Summary Prepared:	October 26, 2000
(2) Trade or proprietary device name:	Aneroid sphygmomanometer with stethoscope
Common or usual name:	Aneroid sphygmomanometer (and stethoscope)
Classification name:	Noninvasive blood pressure monitor
Panel:	Cardiovascular
(3) Legally marketed predicate device:	OMRON Self-taking blood pressure monitor (OMRON Healthcare, Inc.)

(4) Subject device description:

The Aneroid sphygmomanometer with stethoscope is a noninvasive blood pressure measurement system for monitoring blood pressure levels which can be performed by the individual using it.

The Aneroid sphygmomanometer with stethoscope contains:

1. Adjustable D-ring cuff (adult size)
2. Stethoscope (attaches to the cuff)
3. Non-stop rotary pin, 300mmHg gauge
4. Instruction booklet and record
5. Carrying case

The Aneroid sphygmomanometer with stethoscope enables the user to monitor the pressure of flowing blood that is exerted against the arteries at highest (systolic or contraction) and lowest (diastolic or relaxation) pressure.

To operate, the user places the attached stethoscope on the inner arm above the bend in the elbow, to detect the pulse of the brachial artery. After inflation of the cuff, the user does auditory monitoring with the stethoscope to evaluate systolic and diastolic pressure. The two values are usually recorded as a ratio of the two measurements: systolic over diastolic.

(5) Subject device intended use:

The Aneroid sphygmomanometer with stethoscope is a noninvasive blood pressure measurement system for monitoring blood pressure levels which can be performed by the individual using it.

(6) Statement of Compliance to voluntary and internation standards for Non-automated sphygmomanometers:

The Aneroid sphygmomanometer with stethoscope has been tested to conform to current harmonized standards, EN 1060.1 and EN 1060.2, Requirements for non-invasive sphygmomanometers and mechanical sphygmomanometers. These standards are equivalent to the ANSI/AAMI Standard SP-9, Non-automated sphygmomanometer. Therefore, the device also meets or exceeds ANSI/AAMI Standard SP-9.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN - 3 2001

Ms. Ann D. McGonigle
Wang & Li, Inc.
2026 Coyle St.
Brooklyn, NY 11229

Re: K003415
Trade Name: Aneroid Sphygmomanometer
Regulatory Class: II (two)
Product Code: DXQ
Dated: October 26, 2000
Received: November 2, 2000

Dear Ms. McGonigle:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. Indications for use of the Device

510(k) Number): ~~Not known~~ K003415

Device Name: Aneroid sphygmomanometer with stethoscope

Indications for Use:

The Aneroid sphygmomanometer with stethoscope is a noninvasive blood pressure measurement system for monitoring blood pressure levels which can be performed by the individual using it.

(Please do not write below this line—continue on another page if needed)

* * * * * * * * * *

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003415

Prescription Use _____ **or** **Over-the-counter Use** X
(Per 21 CFR 801.109) (Optional Format 1-2-96)